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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, ASTRAZENECA LP, KBI-E INC., and POZEN INC., *Plaintiffs*, v. LUPIN LTD. and LUPIN PHARMACEUTICALS INC., *Defendants*.	Civil Case No. 11-cv-04275 (JAP) (DEA) **DOCUMENT FILED ELECTRONICALLY** Hon. Joel A. Pisano, U.S.D.J. Hon. Douglas E. Arpert, U.S.M.J.

ANSWER AND COUNTERCLAIMS

Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. ("LPI") (collectively, "Lupin"), by and through their attorneys, respond to each of the numbered paragraphs in the Complaint by

Plaintiffs AstraZeneca AB, AstraZeneca LP, KBI-E Inc., and Pozen Inc. (collectively, "Plaintiffs") as follows:

NATURE OF THE ACTION

1. Lupin admits that this action arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and that it relates to Abbreviated New Drug Application ("ANDA") No. 202654 submitted by Lupin Ltd. to the United States Food and Drug Administration ("FDA"), seeking approval to market esomeprazole magnesium and delayed-release naproxen tablets (20 mg/375 mg and 20 mg/500 mg) ("the esomeprazole magnesium and delayed-release naproxen tablets") in the United States. Lupin further admits that VIMOVO® products are currently marketed in the United States, but Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 1 of the Complaint and, therefore, denies them.

THE PARTIES

2. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 of the Complaint and, therefore, denies them.

3. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3 of the Complaint and, therefore, denies them.

4. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 4 of the Complaint and, therefore, denies them.

5. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 5 of the Complaint and, therefore, denies them.

6. Lupin admits that Lupin Ltd. is a company organized and existing under the laws of India, has a principal place of business at Laxmi Towers, "B" Wing, 5th Floor, Bandra Kurla

Complex, Mumbai 400 051, India, and has a registered office at 159 CST Road, Kalina, Santacruz (East), Mumbai 400 098, India. Lupin denies the remaining allegations in paragraph 6 of the Complaint.

7. Lupin admits that LPI is a corporation organized and existing under the laws of the Commonwealth of Virginia, with a principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. Lupin denies the remaining allegations in paragraph 7 of the Complaint.

8. Admitted.

BACKGROUND

The NDA

9. Lupin admits that the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" ("the Orange Book") lists "Astrazeneca LP" as the applicant in connection with Application No. 022511 (Proprietary Name: VIMOVO®), with the dosage form, active ingredients, and strengths thereof being described in the Orange Book as "tablet, delayed release," "esomeprazole magnesium; naproxen," and "eq 20 mg; 375 mg" and "eq 20 mg; 500 mg," respectively. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 9 of the Complaint and, therefore, denies them.

10. Lupin admits that VIMOVO® is approved for marketing by the FDA, but Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 10 of the Complaint and, therefore, denies them.

The Patents in Suit

11. Lupin admits that United States Patent No. 5,714,504 ("the '504 patent") is entitled "Compositions," and was issued by the United States Patent and Trademark Office ("USPTO") on February 3, 1998. Lupin also admits that what is represented to be a copy of the '504 patent is attached to the Complaint as Exhibit A. The remaining allegations in paragraph 11 of the Complaint state legal conclusions to which no answer is required. To the extent an answer to any factual allegation is required, Lupin denies same.

12. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 12 of the Complaint and, therefore, denies them.

13. Lupin admits that United States Patent No. 6,875,872 ("the '872 patent") is entitled "Compounds," and was issued by the USPTO on April 5, 2005. Lupin also admits that what is represented to be a copy of the '872 patent is attached to the Complaint as Exhibit B. The remaining allegations in paragraph 13 of the Complaint state legal conclusions to which no answer is required. To the extent an answer to any factual allegation is required, Lupin denies same.

14. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 14 of the Complaint and, therefore, denies them.

15. Lupin admits that United States Patent No. 6,369,085 ("the '085 patent") is entitled "Form of S-omeprazole," and was issued by the USPTO on April 9, 2002. Lupin also admits that what is represented to be a copy of the '085 patent is attached to the Complaint as Exhibit C. The remaining allegations in paragraph 15 of the Complaint state legal conclusions to which no answer is required. To the extent an answer to any factual allegation is required, Lupin denies same.

16. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 16 of the Complaint and, therefore, denies them.

17. Lupin admits that United States Patent No. 7,411,070 ("the '070 patent") is entitled "Form of S-omeprazole," and was issued by the USPTO on August 12, 2008. Lupin also admits that what is represented to be a copy of the '070 patent is attached to the Complaint as Exhibit D. The remaining allegations in paragraph 17 of the Complaint state legal conclusions to which no answer is required. To the extent an answer to any factual allegation is required, Lupin denies same.

18. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 18 of the Complaint and, therefore, denies them.

19. Lupin admits that United States Patent No. 7,745,466 ("the '466 patent") is entitled "Form of S-omeprazole," and was issued by the USPTO on June 29, 2010. Lupin also admits that what is represented to be a copy of the '466 patent is attached to the Complaint as Exhibit E. The remaining allegations in paragraph 19 of the Complaint state legal conclusions to which no answer is required. To the extent an answer to any factual allegation is required, Lupin denies same.

20. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 20 of the Complaint and, therefore, denies them.

21. Lupin admits that United States Patent No. 6,926,907 ("the '907 patent") is entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs," and was issued by the USPTO on August 9, 2005. Lupin also admits that what is represented to be a copy of the '907 patent is attached to the Complaint as Exhibit F. The remaining allegations in

paragraph 21 of the Complaint state legal conclusions to which no answer is required. To the extent an answer to any factual allegation is required, Lupin denies same.

22. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 22 of the Complaint and, therefore, denies them.

The ANDA

23. Lupin admits that Lupin Ltd.'s ANDA No. 202654 was filed with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval to engage in the commercial manufacture, use or sale of the esomeprazole magnesium and delayed-release naproxen tablets in the United States. Lupin denies the remaining allegations in paragraph 23 of the Complaint.

24. Lupin admits that, by letter dated June 10, 2011, Lupin advised Plaintiffs that it had filed ANDA No. 202654 which seeks approval for marketing the esomeprazole magnesium and delayed-release naproxen tablets in the United States, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Lupin denies the remaining allegations in paragraph 24 of the Complaint.

JURISDICTION AND VENUE

25. For the purposes of this action only, Lupin does not contest subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a). Lupin denies the remaining allegations in paragraph 25 of the Complaint.

26. Lupin admits that Lupin Ltd. is in the business of developing, formulating, manufacturing, marketing, offering to sell, selling and commercializing pharmaceutical products, and that LPI markets, offers for sale and sells pharmaceutical products, but denies the remaining allegations in paragraph 26 of the Complaint.

27. For the purposes of this action only, Lupin does not contest personal jurisdiction, but denies the remaining allegations in paragraph 27 of the Complaint.

28. For the purposes of this action only, Lupin does not contest personal jurisdiction, but denies the remaining allegations in paragraph 28 of the Complaint.

29. Lupin admits that LPI is designated as Lupin Ltd.'s U.S. agent in Lupin Ltd.'s ANDA No. 202654 which seeks FDA approval to market the esomeprazole magnesium and delayed-release naproxen tablets in the United States. Lupin denies the remaining allegations in paragraph 29 of the Complaint.

30. Lupin admits that it submitted Lupin Ltd.'s ANDA No. 202654 seeking FDA approval to market the esomeprazole magnesium and delayed-release naproxen tablets in the United States. Lupin further admits that the FDA received ANDA No. 202654. The remaining allegations in paragraph 30 of the Complaint state legal conclusions to which no answer is required. To the extent an answer to any factual allegation is required, Lupin denies them.

31. Lupin admits the allegations in paragraph 31 of the Complaint.

32. For the purposes of this action only, Lupin does not contest personal jurisdiction, but denies the remaining allegations in paragraph 32 of the Complaint.

33. For the purposes of this action only, Lupin does not contest personal jurisdiction, but denies the remaining allegations in paragraph 33 of the Complaint.

34. Lupin admits the allegations in paragraph 34 of the Complaint.

35. For the purposes of this action only, Lupin does not contest personal jurisdiction, but denies the remaining allegations in paragraph 35 of the Complaint.

36. For the purposes of this action only, Lupin does not contest personal jurisdiction, but denies the remaining allegations in paragraph 36 of the Complaint.

37. For the purposes of this action only, Lupin does not contest personal jurisdiction, but denies the remaining allegations in paragraph 37 of the Complaint.

38. Lupin does not contest venue in this action.

COUNT I
(INFRINGEMENT OF THE '504 PATENT UNDER 35 U.S.C. § 271(e)(2)(A))

39. Lupin incorporates by reference its responses to paragraphs 1-38 of the Complaint as if fully set forth herein.

40. Lupin admits that, by letter dated June 10, 2011, Lupin advised Plaintiffs that it submitted Lupin Ltd.'s ANDA No. 202654 which seeks approval for marketing the esomeprazole magnesium and delayed-release naproxen tablets in the United States, and that ANDA No. 202654 included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '504 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of the esomeprazole magnesium and delayed-release naproxen tablets that are the subject of ANDA No. 202654. Lupin also admits that 21 U.S.C. § 355(j)(2)(A)(vii)(IV) states that an ANDA shall contain "a certification . . . that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." Lupin further admits that 21 U.S.C. § 355(j)(2)(B)(iv)(ii) states that "[a] notice required under this subsection shall . . . include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Lupin further admits that 21 C.F.R. § 314.95(c) states that such notice shall include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed," and that the detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed," and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." Lupin denies the remaining allegations of paragraph 40 of the Complaint.

41. Lupin admits the allegations in paragraph 41 of the Complaint.

42. Lupin admits that its letter dated June 10, 2010, asserts that the '504 patent is invalid, unenforceable and/or will not be infringed by the drug products described in Lupin Ltd.'s ANDA No. 202654, and denies the remaining allegations in paragraph 42 of the Complaint.

43. Paragraph 43 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 43 of the Complaint, Lupin denies them.

44. Paragraph 44 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 44 of the Complaint, Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 44 of the Complaint and, therefore, denies them.

45. Paragraph 45 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 45 of the Complaint, Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 45 of the Complaint and, therefore, denies them.

46. The allegations in paragraph 46 of the Complaint state legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 46 of the Complaint, Lupin denies them.

47. The allegations in paragraph 47 of the Complaint state legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 47 of the Complaint, Lupin denies them.

COUNT II
(INFRINGEMENT OF THE '872 PATENT UNDER 35 U.S.C. § 271(e)(2)(A))

48. Lupin incorporates by reference its responses to paragraphs 1-38 of the Complaint as if fully set forth herein.

49. Lupin admits that, by letter dated June 10, 2011, Lupin advised Plaintiffs that it submitted Lupin Ltd.'s ANDA No. 202654, which seeks approval for marketing the esomeprazole magnesium and delayed-release naproxen tablets in the United States, and that ANDA No. 202654 included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '872 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of the esomeprazole magnesium and delayed-release naproxen tablets that are the subject of ANDA No. 202654. Lupin also admits that 21 U.S.C. § 355(j)(2)(A)(vii)(IV) states that an ANDA shall contain "a certification . . . that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." Lupin further admits that 21 U.S.C. § 355(j)(2)(B)(iv)(ii) states that "[a] notice required under this subsection shall . . . include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Lupin further admits that 21 C.F.R. § 314.95(c) states that such notice shall include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed," and that the detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed," and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." Lupin denies the remaining allegations of paragraph 49 of the Complaint.

50. Lupin admits the allegations in paragraph 50 of the Complaint.

51. Lupin admits that its letter dated June 10, 2010, asserts that the '872 patent is invalid, unenforceable and/or will not be infringed by the drug products described in Lupin Ltd.'s ANDA No. 202654, and denies the remaining allegations in paragraph 51 of the Complaint.

52. Paragraph 52 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 52 of the Complaint, Lupin denies them.

53. Paragraph 53 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 53 of the Complaint, Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 53 of the Complaint and, therefore, denies them.

54. Paragraph 54 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 54 of the Complaint, Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 54 of the Complaint and, therefore, denies them.

55. Paragraph 55 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 55 of the Complaint, Lupin denies them.

56. Paragraph 56 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 56 of the Complaint, Lupin denies them.

COUNT III
(INFRINGEMENT OF THE '085 PATENT UNDER 35 U.S.C. § 271(e)(2)(A))

57. Lupin incorporates by reference its responses to paragraphs 1-38 of the Complaint as if fully set forth herein.

58. Lupin admits that, by letter dated June 10, 2011, Lupin advised Plaintiffs that it submitted Lupin Ltd.'s ANDA No. 202654, which seeks approval for marketing the esomeprazole magnesium and delayed-release naproxen tablets in the United States, and that ANDA No. 202654 included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '085 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of the esomeprazole magnesium and delayed-release naproxen tablets that are the subject of ANDA No. 202654. Lupin also admits that 21 U.S.C. § 355(j)(2)(A)(vii)(IV) states that an ANDA shall contain "a certification . . . that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." Lupin further admits that 21 U.S.C. § 355(j)(2)(B)(iv)(ii) states that "[a] notice required under this subsection shall . . . include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Lupin further admits that 21 C.F.R. § 314.95(c) states that such notice shall include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed," and that the detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed," and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." Lupin denies the remaining allegations of paragraph 58 of the Complaint.

59. Lupin admits the allegations in paragraph 59 of the Complaint.

60. Lupin denies the allegations in Paragraph 60 of the Complaint.

61. Paragraph 61 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 61 of the Complaint, Lupin denies them.

62. Paragraph 62 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 62 of the Complaint, Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 62 of the Complaint and, therefore, denies them.

63. Paragraph 63 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 63 of the Complaint, Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 63 of the Complaint and, therefore, denies them.

64. Paragraph 64 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 64 of the Complaint, Lupin denies them.

65. Paragraph 65 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 65 of the Complaint, Lupin denies them.

COUNT IV
(INFRINGEMENT OF THE '070 PATENT UNDER 35 U.S.C. § 271(e)(2)(A))

66. Lupin incorporates by reference its responses to paragraphs 1-38 of the Complaint as if fully set forth herein.

67. Lupin admits that, by letter dated June 10, 2011, Lupin advised Plaintiffs that it submitted Lupin Ltd.'s ANDA No. 202654 which seeks approval for marketing the

esomeprazole magnesium and delayed-release naproxen tablets in the United States, and that ANDA No. 202654 included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '070 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of the esomeprazole magnesium and delayed-release naproxen tablets that are the subject of ANDA No. 202654. Lupin also admits that 21 U.S.C. § 355(j)(2)(A)(vii)(IV) states that an ANDA shall contain "a certification . . . that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." Lupin further admits that 21 U.S.C. § 355(j)(2)(B)(iv)(ii) states that "[a] notice required under this subsection shall . . . include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Lupin further admits that 21 C.F.R. § 314.95(c) states that such notice shall include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed," and that the detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed," and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." Lupin denies the remaining allegations of paragraph 67 of the Complaint.

68. Lupin admits the allegations in paragraph 68 of the Complaint.

69. Lupin denies the allegations in Paragraph 69 of the Complaint.

70. Paragraph 70 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 70 of the Complaint, Lupin denies them.

71. Paragraph 71 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 71 of the Complaint, Lupin denies them.

72. Paragraph 72 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 72 of the Complaint, Lupin denies them.

73. Paragraph 73 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 73 of the Complaint, Lupin denies them.

74. Paragraph 74 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 74 of the Complaint, Lupin denies them.

COUNT V
(INFRINGEMENT OF THE '466 PATENT UNDER 35 U.S.C. § 271(e)(2)(A))

75. Lupin incorporates by reference its responses to paragraphs 1-38 of the Complaint as if fully set forth herein.

76. Lupin admits that, by letter dated June 10, 2011, Lupin advised Plaintiffs that it submitted Lupin Ltd.'s ANDA No. 202654, which seeks approval for marketing the esomeprazole magnesium and delayed-release naproxen tablets in the United States, and that ANDA No. 202654 included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '466 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of the esomeprazole magnesium and delayed-release naproxen tablets that are the subject of ANDA No. 202654. Lupin also admits that 21 U.S.C. § 355(j)(2)(A)(vii)(IV) states that an ANDA shall contain "a certification . . . that such patent is invalid or will not be infringed by the manufacture,

use, or sale of the new drug for which the application is submitted." Lupin further admits that 21 U.S.C. § 355(j)(2)(B)(iv)(ii) states that "[a] notice required under this subsection shall . . . include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Lupin further admits that 21 C.F.R. § 314.95(c) states that such notice shall include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed," and that the detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed," and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." Lupin denies the remaining allegations of paragraph 76 of the Complaint.

77. Lupin admits the allegations in paragraph 77 of the Complaint.

78. Lupin denies the allegations in Paragraph 78 of the Complaint.

79. Paragraph 79 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 79 of the Complaint, Lupin denies them.

80. Paragraph 80 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 80 of the Complaint, Lupin denies them.

81. Paragraph 81 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 81 of the Complaint, Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 81 of the Complaint and, therefore, denies them.

82. Paragraph 82 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 82 of the Complaint, Lupin denies them.

83. Paragraph 83 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 83 of the Complaint, Lupin denies them.

COUNT VI
(INFRINGEMENT OF THE '907 PATENT UNDER 35 U.S.C. § 271(e)(2)(A))

84. Lupin incorporates by reference its responses to paragraphs 1-38 of the Complaint as if fully set forth herein.

85. Lupin admits that, by letter dated June 10, 2011, Lupin advised Plaintiffs that it submitted Lupin Ltd.'s ANDA No. 202654 which seeks approval for marketing the esomeprazole magnesium and delayed-release naproxen tablets in the United States, and that ANDA No. 202654 included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '907 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of the esomeprazole magnesium and delayed-release naproxen tablets that are the subject of ANDA No. 202654. Lupin also admits that 21 U.S.C. § 355(j)(2)(A)(vii)(IV) states that an ANDA shall contain "a certification . . . that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." Lupin further admits that 21 U.S.C. § 355(j)(2)(B)(iv)(ii) states that "[a] notice required under this subsection shall . . . include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Lupin further admits that 21 C.F.R. § 314.95(c) states that such notice shall include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed," and that

the detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed," and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." Lupin denies the remaining allegations of paragraph 85 of the Complaint.

86. Lupin admits the allegations in paragraph 86 of the Complaint.

87. Lupin admits that its letter dated June 10, 2010, asserts that the '907 patent is invalid, unenforceable and/or will not be infringed by the drug products described in Lupin Ltd.'s ANDA No. 202654, and denies the remaining allegations in paragraph 87 of the Complaint.

88. Paragraph 88 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 88 of the Complaint, Lupin denies them.

89. Paragraph 89 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 89 of the Complaint, Lupin denies them.

90. Paragraph 90 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 90 of the Complaint, Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 90 of the Complaint and, therefore, denies them.

91. Paragraph 91 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 91 of the Complaint,

Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 91 of the Complaint and, therefore, denies them.

92. Paragraph 92 of the Complaint states legal conclusions to which no answer is required. To the extent any factual assertions are included in paragraph 92 of the Complaint, Lupin denies them.

PRAYER FOR RELIEF

Lupin denies that Plaintiffs are entitled to the judgment and relief requested in the Prayer for Relief set forth in the Complaint.

AFFIRMATIVE AND SEPARATE DEFENSES

Without prejudice to the denials set forth in its responses to paragraphs 1 through 92 of the Complaint, Lupin alleges the following Affirmative and Separate Defenses to the Complaint.

First Defense
(Invalidity of the '504 Patent)

93. Each claim of the '504 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and 112, and/or double patenting.

Second Defense
(Noninfringement of the '504 Patent)

94. Lupin, and the esomeprazole magnesium and delayed-release naproxen tablets that are the subject of ANDA No. 202654, do not infringe any valid and enforceable claim of the '504 patent.

Third Defense
(Invalidity of the '085 Patent)

95. Each claim of the '085 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and 112, and/or double patenting.

Fourth Defense
(Noninfringement of the '085 Patent)

96. Lupin, and the esomeprazole magnesium and delayed-release naproxen tablets that are the subject of ANDA No. 202654, do not infringe any valid and enforceable claim of the '085 patent.

Fifth Defense
(Invalidity of the '872 Patent)

97. Each claim of the '872 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and 112, and/or double patenting.

Sixth Defense
(Noninfringement of the '872 Patent)

98. Lupin, and the esomeprazole magnesium and delayed-release naproxen tablets that are the subject of ANDA No. 202654, do not infringe any valid and enforceable claim of the '872 patent.

Seventh Defense
(Invalidity of the '070 Patent)

99. Each claim of the '070 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and 112, and/or double patenting.

Eighth Defense
(Noninfringement of the '070 Patent)

100. Lupin, and the esomeprazole magnesium and delayed-release naproxen tablets that are the subject of ANDA No. 202654, do not infringe any valid and enforceable claim of the '070 patent.

Ninth Defense
(Invalidity of the '466 Patent)

101. Each claim of the '466 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and 112, and/or double patenting.

Tenth Defense
(Noninfringement of the '466 Patent)

102. Lupin, and the esomeprazole magnesium and delayed-release naproxen tablets that are the subject of ANDA No. 202654, do not infringe any valid and enforceable claim of the '466 patent.

Eleventh Defense
(Invalidity of the '907 Patent)

103. Each claim of the '907 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and 112, and/or double patenting.

Twelfth Defense
(Noninfringement of the '907 Patent)

104. Lupin, and the esomeprazole magnesium and delayed-release naproxen tablets that are the subject of ANDA No. 202654, do not infringe any valid and enforceable claim of the '907 patent.

Thirteenth Defense
(Limitation of Remedies)

105. The remedy of an injunction or other equitable relief sought by Plaintiffs in its Complaint is unavailable to Plaintiffs in this action.

COUNTERCLAIMS

106. Defendants/Counterclaim-Plaintiffs Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively "Lupin") bring the following Counterclaims against Plaintiffs/Counterclaim-Defendants AstraZeneca AB, AstraZeneca LP, KBI-E Inc., and Pozen Inc. (collectively,

"Counterclaim-Defendants"), for a declaratory judgment that the '504 patent, the '085 patent, the '872 patent, the '070 patent, the '466 patent, the '907 patent, and U.S. Patent No. 5,900,424 ("the '424 patent") are invalid and/or not infringed by the esomeprazole magnesium and delayed-release naproxen tablets that are the subject of ANDA No. 202654.

THE PARTIES

107. Counterclaim-Plaintiff Lupin Ltd. is a company organized and existing under the laws of India, has a principal place of business at Laxmi Towers, "B" Wing, 5th Floor, Bandra Kurla Complex, Mumbai 400 051, India, and has a registered office at 159 CST Road, Kalina, Santacruz (East), Mumbai 400 098, India.

108. Counterclaim-Plaintiff Lupin Pharmaceuticals Inc. is a corporation organized and existing under the laws of the Commonwealth of Virginia, with a principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202.

109. Upon information and belief, Counterclaim-Defendant AstraZeneca AB is a corporation operating and existing under the laws of Sweden, with its principal place of business at S-151 85 Södertälje, Sweden.

110. Upon information and belief, Counterclaim-Defendant AstraZeneca LP is a limited partnership operating and existing under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

111. Upon information and belief, Counterclaim-Defendant KBI-E Inc. is a corporation operating and existing under the laws of the State of Delaware, with its principal place of business in Wilmington, Delaware.

112. Upon information and belief, Counterclaim-Defendant Plaintiff Pozen Inc. is a corporation operating and existing under the laws of the State of Delaware, with its principal place of business at 1414 Raleigh Road, Chapel Hill, North Carolina 27517.

BACKGROUND

113. Lupin filed Lupin Ltd.'s ANDA No. 202654 with the FDA seeking approval to market the esomeprazole magnesium and delayed-release naproxen tablets, referencing the approved New Drug Application ("NDA") for VIMOVO®. The ANDA provides data showing that the esomeprazole magnesium and delayed-release naproxen tablets are bioequivalent to VIMOVO®, which is the subject of NDA No. 022511.

114. The '504 patent, the '085 patent, the '872 patent, the '070 patent, the '466 patent, the '907 patent, and the '424 patent are listed in the Patent and Exclusivity Information section of the Orange Book in connection with NDA No. 022511 for VIMOVO®. Upon information and belief, AstraZeneca LP listed those patents, and in so doing, contends that the claims of those patents describe and cover the drug VIMOVO®, or a method of using that drug, and that a suit for infringement could reasonably be brought against any generic manufacturer that attempts to seek approval to market a generic version of VIMOVO® before any of the aforementioned patents expire. *See* 21 U.S.C. § 355(b)(1)-(c)(2).

115. Lupin has filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification ("a paragraph IV certification") alleging that the claims of the '504 patent, the '085 patent, the '872 patent, the '070 patent, the '466 patent, the '907 patent, and the '424 patent are invalid and/or not infringed by the esomeprazole magnesium and delayed-release naproxen tablets that are the subject of ANDA No. 202654.

116. On or about June 10, 2011, Lupin provided to Counterclaim-Defendants the statutorily-mandated notice letter concerning its paragraph IV certification on each of these patents. The notice letter met the statutory requirement for such notice letters, and included a detailed statement of the factual and legal bases for Lupin's opinion that, *inter alia*, the '504 patent, the '085 patent, the '872 patent, the '070 patent, the '466 patent, the '907 patent, and the '424 patent are invalid and/or not infringed by the esomeprazole magnesium and delayed-release naproxen tablets that are the subject of ANDA No. 202654.

JURISDICTION AND VENUE

117. Lupin re-alleges and incorporates by reference the allegations of paragraphs 105-115.

118. Counterclaim-Defendants have brought an action against Lupin for allegedly infringing the '504 patent, the '085 patent, the '872 patent, the '070 patent, the '466 patent, and the '907 patent. There exists an actual case or controversy between Lupin and Counterclaim-Defendants as to Lupin's alleged infringement of the '504 patent, the '085 patent, the '872 patent, the '070 patent, the '466 patent, and the '907 patent.

119. There further exists an actual case or controversy between Lupin and Counterclaim-Defendants as to the '424 patent based on AstraZeneca LP's listing of this patent in the Orange Book in connection with NDA No. 022511 for VIMOVO®.

120. This Court has subject matter jurisdiction over the counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 2201, 2202, 1331, 1338(a) and 1367, based on an actual controversy between Lupin and Counterclaim-Defendants arising under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq*.

121. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b), and by Counterclaim-Defendants' choice of forum.

LUPIN IS ENTITLED TO DECLARATORY JUDGMENT

122. On July 25, 2011, Counterclaim-Defendants filed the present lawsuit in this Court against Lupin Ltd. and LPI alleging patent infringement of the '504 patent, the '085 patent, the '872 patent, the '070 patent, the '466 patent, and the '907 patent only by Lupin Ltd.'s filing of ANDA No. 202654 for a generic version of VIMOVO®. Counterclaim-Defendants did not bring a lawsuit alleging infringement of the '424 patent by Lupin Ltd.'s filing of ANDA No. 202654 for a generic version of VIMOVO®. But by listing this patent in the Orange Book in connection with NDA No. 022511 for VIMOVO®, AstraZeneca LP maintains that the claims of this patent describe and cover VIMOVO®, or a method of using VIMOVO®, and that a suit for infringement could reasonably be brought against any ANDA applicant that attempts to seek approval to market a generic version of VIMOVO® before the aforementioned patent expires. *See* 21 U.S.C. § 355(b)(1)-(c)(2). AstraZeneca LP's listing of the '424 patent in the Orange Book in connection with NDA No. 022511 creates the requisite justiciable case or controversy and subject matter jurisdiction for a generic manufacturer that makes a paragraph IV certification on these patents to bring a declaratory judgment action.

123. A generic manufacturer, like Lupin Ltd., that has submitted an ANDA containing a paragraph IV certification on a patent is entitled to bring and maintain a declaratory judgment action against the NDA holder/patent holder on that patent if the following have occurred: (1) 45 days have elapsed since the paragraph IV certification was received by the NDA holder/patent holder; (2) neither the NDA holder nor the patent holder has filed a suit for patent infringement on the patent subject to the paragraph IV certification within the 45-day period; and (3) an offer

of confidential access to the ANDA is included in the notice of paragraph IV certification provided to the NDA holder/patent holder. *See* 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa)-(cc).

124. Because Lupin Ltd. has provided the offer to confidential access to its ANDA pursuant to 21 U.S.C. § 355(i)(5)(C)(i)(III) in its notice of paragraph IV certification, and Counterclaim-Defendants did not sue Lupin Ltd. on the '424 patent within 45 days of receiving Lupin Ltd.'s notice of paragraph IV certification, Lupin Ltd. is statutorily permitted to bring and maintain a declaratory judgment action against Counterclaim-Defendants pursuant to 21 U.S.C. § 355(j)(5)(C).

125. Lupin Ltd. further requires a court decision of noninfringement and/or invalidity on the '424 patent to prevent it from risking infringement liability on this patent if (and when) it begins marketing its generic version of VIMOVO® before this patent expires. This harm can be alleviated through a declaration of patent certainty on noninfringement and/or invalidity from this Court on the '424 patent.

FIRST COUNTERCLAIM
(Declaration of Noninfringement of the '504 Patent)

126. Lupin incorporates by reference the allegations set forth in paragraphs 106 through 125 of the Counterclaims as if fully set forth herein.

127. Lupin, and the esomeprazole magnesium and delayed-release naproxen tablets that are the subject of ANDA No. 202654, do not infringe any valid and enforceable claim of the '504 patent.

128. There is an actual case or controversy as to the noninfringement of the '504 patent.

SECOND COUNTERCLAIM
(Declaration of Invalidity of the '504 Patent)

129. Lupin incorporates by reference the allegations set forth in paragraphs 106 through 125 of the Counterclaims as if fully set forth herein.

130. All claims of the '504 patent are invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and 112 and/or double patenting.

131. There is an actual case or controversy as to the validity of all claims of the '504 patent.

THIRD COUNTERCLAIM
(Declaration of Noninfringement of the '085 Patent)

132. Lupin incorporates by reference the allegations set forth in paragraphs 106 through 125 of the Counterclaims as if fully set forth herein.

133. Lupin, and the esomeprazole magnesium and delayed-release naproxen tablets that are the subject of ANDA No. 202654, do not infringe any valid and enforceable claim of the '085 patent.

134. There is an actual case or controversy as to the noninfringement of the '085 patent.

FOURTH COUNTERCLAIM
(Declaration of Invalidity of the '085 Patent)

135. Lupin incorporates by reference the allegations set forth in paragraphs 106 through 125 of the Counterclaims as if fully set forth herein.

136. All claims of the '085 patent are invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and 112 and/or double patenting.

137. There is an actual case or controversy as to the validity of all claims of the '085 patent.

FIFTH COUNTERCLAIM
(Declaration of Noninfringement of the '872 Patent)

138. Lupin incorporates by reference the allegations set forth in paragraphs 106 through 125 of the Counterclaims as if fully set forth herein.

139. Lupin, and the esomeprazole magnesium and delayed-release naproxen tablets that are the subject of ANDA No. 202654, do not infringe any valid and enforceable claim of the '872 patent.

140. There is an actual case or controversy as to the noninfringement of the '872 patent.

SIXTH COUNTERCLAIM
(Declaration of Invalidity of the '872 Patent)

141. Lupin incorporates by reference the allegations set forth in paragraphs 106 through 125 of the Counterclaims as if fully set forth herein.

142. All claims of the '872 patent are invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and 112 and/or double patenting.

143. There is an actual case or controversy as to the validity of all claims of the '872 patent.

SEVENTH COUNTERCLAIM
(Declaration of Noninfringement of the '070 Patent)

144. Lupin incorporates by reference the allegations set forth in paragraphs 106 through 125 of the Counterclaims as if fully set forth herein.

145. Lupin, and the esomeprazole magnesium and delayed-release naproxen tablets that are the subject of ANDA No. 202654, do not infringe any valid and enforceable claim of the '070 patent.

146. There is an actual case or controversy as to the noninfringement of the '070 patent.

EIGHTH COUNTERCLAIM
(Declaration of Invalidity of the '070 Patent)

147. Lupin incorporates by reference the allegations set forth in paragraphs 106 through 125 of the Counterclaims as if fully set forth herein.

148. All claims of the '070 patent are invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and 112 and/or double patenting.

149. There is an actual case or controversy as to the validity of all claims of the '070 patent.

NINTH COUNTERCLAIM
(Declaration of Noninfringement of the '466 Patent)

150. Lupin incorporates by reference the allegations set forth in paragraphs 106 through 125 of the Counterclaims as if fully set forth herein.

151. Lupin, and the esomeprazole magnesium and delayed-release naproxen tablets that are the subject of ANDA No. 202654, do not infringe any valid and enforceable claim of the '466 patent.

152. There is an actual case or controversy as to the noninfringement of the '466 patent.

TENTH COUNTERCLAIM
(Declaration of Invalidity of the '466 Patent)

153. Lupin incorporates by reference the allegations set forth in paragraphs 106 through 125 of the Counterclaims as if fully set forth herein.

154. All claims of the '466 patent are invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and 112 and/or double patenting.

155. There is an actual case or controversy as to the validity of all claims of the '466 patent.

ELEVENTH COUNTERCLAIM
(Declaration of Noninfringement of the '907 Patent)

156. Lupin incorporates by reference the allegations set forth in paragraphs 106 through 125 of the Counterclaims as if fully set forth herein.

157. Lupin, and the esomeprazole magnesium and delayed-release naproxen tablets that are the subject of ANDA No. 202654, do not infringe any valid and enforceable claim of the '907 patent.

158. There is an actual case or controversy as to the noninfringement of the '907 patent.

TWELFTH COUNTERCLAIM
(Declaration of Invalidity of the '907 Patent)

159. Lupin incorporates by reference the allegations set forth in paragraphs 106 through 125 of the Counterclaims as if fully set forth herein.

160. All claims of the '907 patent are invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and 112 and/or double patenting.

161. There is an actual case or controversy as to the validity of all claims of the '907 patent.

THIRTEENTH COUNTERCLAIM
(Declaration of Noninfringement of the '424 Patent)

162. Lupin incorporates by reference the allegations set forth in paragraphs 106 through 125 of the Counterclaims as if fully set forth herein.

163. Lupin, and the esomeprazole magnesium and delayed-release naproxen tablets that are the subject of ANDA No. 202654, do not infringe any valid and enforceable claim of the '424 patent.

164. There is an actual case or controversy as to the noninfringement of the '424 patent.

FOURTEENTH COUNTERCLAIM
(Declaration of Invalidity of the '424 Patent)

165. Lupin incorporates by reference the allegations set forth in paragraphs 106 through 125 of the Counterclaims as if fully set forth herein.

166. All claims of the '424 patent are invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and 112 and/or double patenting.

167. There is an actual case or controversy as to the validity of all claims of the '424 patent.

PRAYER FOR RELIEF

WHEREFORE, Lupin prays that this Court enter a judgment against Plaintiffs/Counterclaim-Defendants:

A. Declaring that the claims of the '504 patent, the '085 patent, the '872 patent, the '070 patent, the '466 patent, the '907 patent, and the '424 patent are invalid;

B. Declaring that Lupin, and the esomeprazole magnesium and delayed-release naproxen tablets that are the subject of ANDA No. 202654, do not infringe any valid and enforceable claim of the '504 patent, the '085 patent, the '872 patent, the '070 patent, the '466 patent, the '907 patent, and the '424 patent;

C. Awarding Lupin its costs and expenses incurred in this action;

D. Declaring that this case is an exception case under 35 U.S.C. § 285 and awarding Lupin its attorney's fees, costs, and expenses; and

F. Awarding Lupin such other and further relief as the Court may deem proper.

STERNS & WEINROTH,
A Professional Corporation
Attorneys for Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc.

Dated: September 26, 2011

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1 OF LUPIN LTD. AND PHARMACEUTICALS, INC.

Pursuant to Local Civil Rule 11.2 and 40.1, Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. by their attorneys, hereby certify to the best of their knowledge and belief that the matter in controversy, particularly the patents-in-suit in the above-captioned matter, is the subject of the following action: *AstraZeneca AB, AstraZeneca LP, KBI-E Inc., and Pozen Inc., v. Dr. Reddy's Laboratories, Ltd and Dr. Reddy's Laboratories, Inc.* Civil Case No. 3-11-cv-02317 (JAP)(LHG).

Dated: September 26, 2011

/s/ Karen A. Confoy
Karen A. Confoy
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CERTIFICATE OF SERVICE

I hereby certify that counsel of record for plaintiffs were served with this document on this date via CM/ECF.

Dated: September 26, 2011

/s/ Karen A. Confoy
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